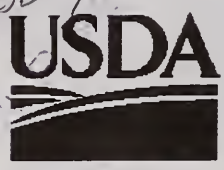

Meat and Poultry Inspection Regulations

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Field
Operations

Combined Changes 96-1 through 96-5

September, 1997

PART 312-OFFICIAL MARKS, DEVICES AND CERTIFICATES

PART 313-HUMANE SLAUGHTER OF LIVESTOCK

PART 314-HANDLING AND DISPOSAL OF CONDEMNED OR OTHER INEDIBLE PRODUCTS AT OFFICIAL ESTABLISHMENTS

PART 315-RENDERING OR OTHER DISPOSAL OF CARCASSES AND PARTS PASSED FOR COOKING

PART 316-MARKING PRODUCTS AND THEIR CONTAINERS

PART 317-LABELING, MARKING DEVICES, AND CONTAINERS

SUBPART A--GENERAL

SUBPART B--NUTRITION LABELING

PART 318-ENTRY INTO OFFICIAL ESTABLISHMENTS: REINSPECTION AND PREPARATION OF PRODUCTS

SUBPART A--GENERAL

§ 306.1 Designation of circuit supervisor and assistants.

The Administrator shall designate a circuit supervisor of the inspection in each circuit, and assign to said inspector such assistants as may be necessary.

§ 306.2 Program employees to have access to establishments.

For the purpose of any examination or inspection necessary to prevent the use in commerce of any adulterated product, Program employees shall have access at all times, by day or night, whether the establishment is operated or not, to every part of any official establishment to which they are assigned. Access to establishments is also authorized in accordance with section 202 of the Act and the regulations in Part 320 of this subchapter.

§ 306.3 Badge as identification of inspectors.

Each inspector will be furnished with a numbered official badge, which he shall not allow to leave his possession, and which he shall wear in such manner and at such times as the Administrator may prescribe. This badge shall be sufficient identification to entitle him to admittance at a all regular entrances and to all parts of the establishment and premises to which he is assigned.

§ 306.4 Assignment of Program employees where members of family employed; soliciting employment; procuring product form official establishments.

(a) Except as specifically authorized by the Administrator, no Program employee shall be detailed for duty at an establishment where any member of his family is employed by the operator of the establishment, or any tenant or subsidiary of such operator nor shall any circuit supervisor or other employee acting in a supervisory capacity be continued on duty at a circuit where any member of his family is so employed at any establishment under his jurisdiction. Program employees are forbidden to solicit, for any person, employment at any official establishment, or by any officer, manager, or employee thereof.

(b) Program employees shall not procure product from any official establishment or any other establishment if its operations or products are inspected or regulated under the Poultry Products Inspection Act or the Agricultural Marketing Act of 1946, as amended, or any other law administered by the Department unless the store or outlet from which the purchase is made is open to the general public and the price paid by such employee is the same as the price paid by the general public. Program employees must pay, and obtain receipts for money paid to such establishments for all such product and keep such receipts subject to inspection by supervisory employees or other authorized Department employees.

§ 306.5 Appeals.

Any appeal from a decision of any Program employee shall be made to his/her immediate supervisor having jurisdiction aver the subject matter of the appeal, except as otherwise provided in the applicable rules of practice.

* * * * *

PART 307-FACILITIES FOR INSPECTION

AUTHORITY: 7 U.S.C. 394; 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

§ 307.1 Facilities for Program employees.

Office space, including necessary furnishings, light, heat, and janitor service, shall be provided by official establishments, rent free, for the exclusive use for official purposes of the inspector and other Program employees assigned thereto. The space set aside for this purpose shall meet with approval of the circuit supervisor and shall be conveniently located, properly ventilated and provided with lockers suitable for the protection and storage of Program supplies and with facilities suitable for Program employees to change clothing if such clothes changing facilities are deemed necessary by the circuit supervisor. At the discretion of the Administrator, small plants requiring the services of less than one full time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Laundry service for inspectors' outer work clothing shall be provided by each establishment.

§ 307.2 Other facilities and conditions to be provided by establishment.

When required by the circuit supervisor, the following facilities and conditions, and such others as may be found to be essential to efficient conduct of inspection and maintenance of sanitary conditions, shall be provided by each official establishment:

(a) Satisfactory pens, equipment, and assistants for conducting antemortem inspection and for separating, marking and holding apart from passed livestock those marked "U.S. suspect" and those marked "U.S. condemned" (pens, alleys, and runways shall be paved, drained, and supplied with adequate hose ,connections for cleanup purposes);

(b) Sufficient light to be adequate for proper conduct of inspection;

(c) Racks, receptacles, or other suitable devices for retaining such parts as the head, tongue, tail, thymus gland, and viscera, and all parts and blood to be used in the preparation of meat food products or medical products, until after the post-mortem examination is completed, in order that they may be identified in case of condemnation of the carcass; equipment, trucks, and receptacles for the handling of viscera of slaughtered animals so as to prevent contact with the floor; and trucks, racks, marked receptacles, tables, and other necessary equipment for the separate and sanitary handling of carcasses or parts passed for cooking;

(d) Tables, benches, and other equipment on which inspection is to be performed, of such design, material, and construction as to enable Program employees to conduct their inspection in a ready, efficient and clean manner;

(e) Watertight metal trucks or receptacles for holding and handling diseased carcasses and parts, so constructed as to be readily cleaned; such

shipping container. The net weight also shall be applied directly to random weight consumer size packages prior to retail display and sale. The net weight statement on random weight consumer size packages for retail sale shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(ii) Individually wrapped and labeled packages of less than 1/2 ounce net weight and random weight consumer size packages shall be exempt from the requirements of this paragraph if they are in a shipping container and the statement of net quantity of contents on the shipping container meets the requirements of paragraph (h)(2)of this section.

(iii) Individually wrapped and labeled packages of less than 1/2 ounce net weight bearing labels declaring net weight, price per pound, and total price, shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(iv) Margarine in 1 pound rectangular packages (except packages containing whipped or soft margarine or packages that contain more than four sticks) is exempt from the requirements of subparagraphs (h)(3) and (5) of this paragraph regarding the placement of the statement of the net quantity of contents within the bottom 30 percent of the principal display panel and that the statement be expressed both in ounces and in pounds, if the statement appears as "1 pound" or "one pound" in a conspicuous manner on the principal display panel.

(v) Sliced shingle packed bacon in rectangular packages is exempt from * the requirements of paragraphs (h)(3) and (5) of this section regarding the * placement of the statement of the net quantity of contents within the bottom * 30 percent of the principal display panel, and that the statement be expressed * * both in ounces and in pounds, if the statement appears in a conspicuous manner * on the principal display panel.

(10) Labels for containers which bear any representation as to the number of servings contained therein shall bear, contiguous to such representation, and in the same size type as is used for such representation, a statement of the net quantity of each such serving.

(11) As used in this section, a "random weight consumer size package" is one which is one of a lot, shipment, or delivery of packages of the same product with varying weights and with no fixed weight pattern.

(12) On a multiunit retail package, a statement of the net quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and in parentheses, the total net quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as required by subparagraph (h)(5) of this section. For the purposes of this section, "multiunit retail package" means a package containing two or more individually packaged units of the

identical commodity and in the same quantity, with the individual packages intended to be sold as part of the multiunit retail package but capable of being individually sold in full compliance with all requirements of the regulations in this part. Open multiunit retail packages that do not obscure the number of units and the labeling thereon are not subject to this paragraph if the labeling of each individual unit complies with the requirements of paragraphs (h) (2), (3), (6), and (8) of this section.

* * *

(i) The official establishment number of the official establishment in which the product was processed under inspection shall be placed as follows:

(1) Within the official inspection legend in the form required by Part 312 of this subchapter; or

(2) Outside the official inspection legend elsewhere on the exterior of the container or its labeling, e.g., the lid of a can, if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition and accompanied by the prefix "EST"; or

(3) Off the exterior of the container, e.g., on a metal clip used to close casings or bags, or on the back of a paper label of a canned product, or on other packaging or labeling material in the container, e.g., on aluminum pans and trays placed within containers, when a statement of its location is printed contiguous to the official inspection legend, such as "EST. No. on Metal Clip" or "Est. No. on Pan", if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition; or

(4) On an insert label placed under a transparent covering if clearly visible and legible and accompanied by the prefix "EST".

(j) Labels of any product within any of the following paragraphs shall show the information required by such paragraph for such product:

(1) A label for product which is an imitation of another food shall bear the word "imitation" immediately preceding the name of the food imitated and in the same size and style of lettering as in that name and immediately thereafter the word "ingredients:" and the names of the ingredients arranged in the order of their predominance.

(2) If a product purports to be or is represented for any special dietary use by man, its label shall bear a statement concerning its vitamin, mineral, and other dietary properties upon which the claim for such use is based in whole or in part and shall be in conformity with regulations (21 CFR Part 125) established pursuant to sections 403, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343, 371).

(3) When an artificial smoke flavoring or a smoke flavoring is added as an ingredient in the formula of a meat food product, as

*U.S. G.P.O.:1996-417-250:40018/FSIS

(§ 317.3 continued)

(3) The manufacturer of the brands or other marking devices shall engrave or otherwise mark each brand or other marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer the number of each brand or other marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy with the brands or other marking devices to the Program employee whose name and address are given on the certificate as the recipient.

(4) In order that all such brands or other marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such brand or other marking device which does not bear an identifying number, or, under the direction of the inspector-in-charge mark such brand or other marking device with a permanent identifying number.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583-0015.)

* § 317.4 Labeling approval. *

(a) No labeling shall be used on any product unless the sketch labeling * of such final labeling has been submitted for approval to the Food Labeling * Division, Regulatory Programs, Food Safety and Inspection Service, and * approved by such division, accompanied by FSIS form, Application for * Approval of Labels, Marking, and Devices, except for generically approved * labeling authorized for use in § 317.5(b). The management of the official * establishment or establishment certified under a foreign inspection system, * in accordance with part 327 of this subchapter, must maintain a copy of all * labeling used, along with the product formulation and processing procedure, * in accordance with part 320 of this subchapter. Such records shall be made * available to any duly authorized representative of the Secretary upon * request. *

* (b) The Food Labeling Division shall permit submission for approval of * only sketch labeling, as defined in § 317.4(d), for all products, except as * provided in § 317.5(b)(2)-(9) and except for temporary use of final * labeling as prescribed in paragraph (f) of this section. *

* (c) All labeling required to be submitted for approval as set forth in * § 317.4(a) shall be submitted in duplicate to the Food Labeling Division, * Regulatory Programs, Food Safety and Inspection Service, U.S. Department of * Agriculture, Washington, DC 20250. A parent company for a corporation may * submit only one labeling application (in duplicate form) for a product * produced in other establishments that are owned by the corporation. *

* (d) "Sketch" labeling is a printer's proof or equivalent which clearly * shows all labeling features, size, location, and indication of final color, * as specified in § 317.2. FSIS will accept sketches that are hand drawn, * computer generated or other reasonable facsimiles that clearly reflect and * project the final version of the labeling. Indication of final color may * be met by: submission of a color sketch, submission of a sketch which * indicates by descriptive language the final colors, or submission with the * sketch of previously approved final labeling that indicates the final * colors. *

* (e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in § 317.4(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in § 317.5(b)(7).
* (f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days, under the following conditions:
* (i) The proposed labeling would not misrepresent the product;
* (ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;
* (iii) Denial of the request would create undue economic hardship; and
* (iv) An unfair competitive advantage would not result from the granting of the temporary approval.
* (2) Extensions of temporary approvals may also be granted by the Food Labeling Division provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.
* (g) The inspector-in-charge shall approve meat carcass ink brands and meat food product ink and burning brands, which comply with parts 312 and 316 of this subchapter.

§ 317.5 Generically approved labeling.

* (a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accordance with this section and shows all mandatory features in a prominent manner as required in § 317.2, and is not otherwise false or misleading in any particular.
* (2) The Food Safety and Inspection Service shall select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with part 327 of this subchapter, as required in § 317.4, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in § 335.12.
* (b) Generically approved labeling is labeling which complies with the following:
* (1) Labeling for a product which has a product standard as specified in part 319 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled in a foreign language;

(2) Labeling for single-ingredient products (such as beef steak or lamb chops) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(3) Labeling for containers of products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;

(4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 316.13;

(5) Labeling for products not intended for human food, provided they comply with part 325 of this subchapter;

(6) Meat inspection legends, which comply with parts 312 and 316 of this subchapter;

(7) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature;

(8) Labeling for consumer test products not intended for sale; and

(9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) The substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement, e.g., "lb." for "pound," or "oz." for "ounce," or of the word "pound" for "lb." or "ounce" for "oz.";

(iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words "prepared for" or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

(iv) Wrappers or other covers bearing pictorial designs, emblematic designs or illustrations, e.g., floral arrangements, illustrations of animals, fireworks, etc. are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

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* (viii) Any change in the net weight, provided the size of the net weight statement complies with § 317.2;
* (ix) The addition, deletion, or amendment of recipe suggestions for the product;
* (x) Any change in punctuation;
* (xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the Food Labeling Division, Regulatory Programs;
* (xii) The addition or deletion of open dating information;
* (xiii) A change in the type of packaging material on which the label is printed;
* (xiv) Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;
* (xv) The deletion of the word "new" on new product labeling;
* (xvi) The addition, deletion, or amendment of special handling statements, provided that the change is consistent with § 317.2(k);
* (xvii) The addition of safe handling instructions as required by § 317.2(l);
* (xviii) Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in parts 318 and 319 of this subchapter;
* (xix) Changes in the color of the labeling, provided that sufficient contrast and legibility remain;
* (xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package;
* (xxi) A change in the establishment number by a corporation or parent company for an establishment under its ownership;
* (xxii) Changes in nutrition labeling that only involve quantitative adjustments to the nutrition labeling information, except for serving sizes, provided the nutrition labeling information maintains its accuracy and consistency;
* (xxiii) Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information; and
* (xxiv) The addition or deletion of a direct translation of the English language into a foreign language for products marked "for export only."

§ 317.6 Approved labels to be used only on products to which they are applicable.

Labels shall be used only on products for which they are approved, and only if they have been approved for such products in accordance with § 317.3: Provided, That existing stocks of labels approved prior to the effective date of this section and the quantity of which has been identified to the circuit supervisor as being in storage on said date at the official establishment or other identified warehouse for the account of the operator

of the official establishment may be used until such stocks are exhausted, but not later than 1 year after the effective date of this section unless such labels conform to all the requirements of this part and Part 319 of this subchapter. The Administrator may upon the show of good cause grant individual extension of time as he deems necessary.

§ 317.7 Products for foreign commerce; printing labels in foreign language permissible; other deviations.

Labels to be affixed to packages of products for foreign commerce may be printed in a foreign language and may show the statement of the quantity of contents in accordance with the usage of the country to which exported and other deviations from the form of labeling required under this part may be approved for such product by the Administrator in specific cases: Provided,

(a) That the proposed labeling accords to the specifications of the foreign purchaser,

(b) That it is not in conflict with the laws of the country to which the product is intended for export, and

(c) That the outside container is labeled to show that it is intended for export; but if such product is sold or offered for sale in domestic commerce, all the requirements of this subchapter apply. The inspection legend and the establishment number shall in all cases appear in English but in addition, may appear literally translated in a foreign language.

§ 317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

(a) No product or any of its wrappers, packaging, or other containers shall bear any false or misleading marking, label, or other labeling and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of origin or quality or is otherwise false or misleading shall appear in any marking or other labeling. No product shall be wholly or partly enclosed in any wrapper, packaging, or other container that is so made, formed, or filled as to be misleading.

(b) The labels and containers of product shall comply with the following provisions, as applicable:

§ 317.13 Storage and distribution of labels and containers bearing official marks.

Labels, wrappers, and containers bearing any official marks, with or without the establishment number, may be transported from one official establishment to any other official establishment provided such shipments are made with the prior authorization of the inspector in charge at point of origin, who will notify the inspector in charge at destination concerning the date of shipment, quantity, and type of labeling material involved. No such material shall be used at the establishment to which it is shipped unless such use conforms with the requirements of this subchapter.

* § 317.14 [Reserved] *

§ 317.15 [Reserved]

§ 317.16 Labeling and containers of custom prepared products.

Products that are custom prepared under § 303.1(a)(2) of this subchapter must be packaged immediately after preparation and must be labeled (in lieu of information otherwise required by this Part 317) with the words "Not for Sale" in lettering not less than three-eighth inch in height. Such exempted custom prepared products or their containers may bear additional labeling provided such labeling is not false or misleading.

§ 317.17 Interpretation and statement of labeling policy for cured products; special labeling requirements concerning nitrate and nitrite.

(a) With respect to sections 1(n), (7), (9), and (12) of the Act and § 317.2, any substance mixed with another substance to cure a product must be identified in the ingredients statement on the label of such product. For example, curing mixtures composed of such ingredients as water, salt, sugar, sodium phosphate, sodium nitrate, and sodium nitrite or other permitted substances which are added to any product, must be identified on the label of the product by listing each such ingredient in accordance with the provisions of § 317.2.

(b) Any product, such as bacon or pepperoni, which is required to be labeled by a common or usual name or descriptive name in accordance with § 317.2(c)(1) of this Part and to which nitrate or nitrite is permitted or required to be added may be prepared without nitrate or nitrite and labeled with such common or usual name or descriptive name when immediately preceded with the term "Uncured" as part of the product name in the same size and style of lettering as the product name, provided that the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate or nitrite, or both.

(c) (1) Products described in paragraph (b) of this section or § 319.2 of this subchapter, which contain no nitrate or nitrite shall bear the statement "No Nitrate or Nitrite Added." This statement shall be adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name.

(2) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall bear, adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name, the statement "Not Preserved-Keep Refrigerated Below 40° F. At All Times" unless they have been thermally processed to F_o 3 or more; they have been fermented or pickled to pH of 4.6 or less; or they have been dried to a water activity of 0.92 or less.

(3) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall not be subject to the labeling requirements of paragraphs (b) and (c) of this section if they contain an amount of salt sufficient to achieve a brine concentration of 10 percent or more.

§ 317.18 Quantity of contents labeling.

Sections 317.18 through 317.22 of this Part prescribe the procedures to be followed for determining net weight compliance and prescribe the reasonable variations from the declared net weight on the labels of immediate containers of products in accordance with section 317.2(h) of this Part.

§ 317.19 Definitions and procedures for determining net weight compliance.

(a) For the purpose of §§ 317.18 through 317.22 of this Part, the reasonable variations allowed, definitions, and procedures to be used in determining net weight and net weight compliance are described in the National Institute of Standards and Technology (NIST) Handbook 133, "Checking the Contents of Packaged Goods," Third Edition, September 1988, and Supplements 1, 2, 3, and 4 dated September 1990, October 1991, October 1992, and October 1994, respectively, which are incorporated by reference, with the exception of the NIST Handbook 133 and Supplements 1, 3, and 4 requirements listed in paragraphs (b) and (c) of this section. Those provisions incorporated by reference herein, are considered mandatory requirements. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. (These materials are incorporated as they exist on the date of approval.) A notice of any change in the Handbook cited herein will be published in the Federal Register. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. It is also available for inspection at the Office of the Federal Register Information Center, Room 8401, 1100 L Street NW., Washington, D.C. 20408.

Class of substance	Substance	Purpose	Products	Amount
	Sodium acid pyrophosphate.	do	do	Do.
	Dipotassium phosphate.	do	do	Do.
	Monopotassium phosphate.	do	do	Do.
	Potassium tripolyphosphate.	do	do	Do.
	Potassium pyrophosphate.	do	do	Do.
	Citric acid (sodium and potassium salts).	To acidify.	Margarine or oleomargarine.	Sufficient for purpose.
	Lactic acid (sodium and potassium salts).	do	do	Do.
	L-Tartaric acid (sodium and sodium potassium salts).	do	do	Do.
	Adipic acid.	do	do	Do.
	Phosphoric acid.	do	do	Do.
	Hydrochioric acid.	do	do	Do.
	Sodium bicarbonate.	To alkalize.	do	Do.
	Sodium carbonate.	do	do	Do.
	Sodium hydroxide.	do	do	Do.
	Potassium carbonate.	do	do	Do.
	Potassium bicarbonate.	do	do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Citric acid.	To preserve cured color during storage.	Cured pork cuts.	Not to exceed 30 percent in water solution used to spray surfaces of cured cuts, prior to packaging, in accordance with 21 CFR 182.1033. (The use of such solution shall not result in the addition of a significant amount of moisture to the product and shall be applied only once to the product.)
* * * * * * * *	Sodium citrate buffered with citric acid to a pH of 5.6.	To inhibit the growth of micro-organisms and retain product flavor during storage.	Cured and uncured, proceeded whole-meat food products, e.g., ham.	Not to exceed 1.3 percent of the formulation weight of the product in accordance with 21 CFR 184.1751.
Proteolytic enzymes.	Aspergillus oryzae.	To soften tissues.	Raw meat cuts.	Solutions consisting of water and approved proteolytic enzymes applied or injected into raw meat cuts shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus flavus-oryzae group.	do	do	Do.
	Bromelin.	do	do	Do.
	Ficin.	do	do	Do.
	Papein.	do	do	Do.

papain or bromelin or pancreatic extract to permit the enzymes contained in these substances to act on the casings to make them less resistant. The casings shall be handled in a clean and sanitary manner throughout and the treatment shall be followed by washing and flushing the casings with water sufficiently to effectively remove the substance used and terminate the enzymatic action.

(4) On account of the invariable presence of bone splinters, detached spinal cords shall not be used in the preparation of edible product other than for rendering where they constitute a suitable raw material.

(5) Testicles if handled as an edible product may be shipped from the official establishment as such, but they shall not be used as an ingredient of a meat food product.

(6) Tonsils shall be removed and shall not be used as ingredients of meat food products.

(7) Blood from livestock prepared in accordance with § 310.20 of this subchapter may be used as an ingredient of a meat food product for which a standard is prescribed in Part 319 of this subchapter, if permitted by such standard, and may be used in any meat food product for which no such standard is prescribed in Part 319 of this subchapter if it is a common and usual ingredient of such product.

(8) Intestines shall not be used as ingredients in any meat food product for which a standard is prescribed in Part 319 of this subchapter and shall not be used in other products unless the products are labeled in accordance with § 317.8(b)(3) of this subchapter.

(9) Poultry products and egg products (other than shell eggs) which are intended for use as ingredients of meat food products shall be considered acceptable for such use only when identified as having been inspected and passed for wholesomeness by the Department under the regulations in 7 CFR Part 59 or 9 CFR Part 362 or 381 and when found to be sound and otherwise acceptable when presented for use. Poultry products and egg products (other than shell eggs) which have not been so inspected and passed for wholesomeness shall not be used in the preparation of such meat food products.

(10) Dry milk products which are intended for use as ingredients of meat food products shall be considered acceptable for such use only when produced in a plant approved by the Department under the regulations in 7 CFR Part 58, and when found to be sound and otherwise acceptable when presented for use. Dry milk products prepared in a plant not so approved shall not be used in the preparation of such meat food products.

(11) (Reserved)

(12) Ingredients for use in any product may not bear or contain any pesticide chemical or other residues in excess of levels permitted in § 318.16.

* (13) Use of "Mechanically Separated (Kind of Poultry)," as defined in § 381.173 of this chapter, in the preparation of meat food products shall accord with § 381.174 and all other applicable provisions of this subchapter. *

§ 318.7 Approval of substances for use in the preparation of products.

(a) (1) No chemical substance may be used in the preparation of any product unless it is approved in this part or Part 319 of this subchapter or by the Administrator in specific cases.

(2) Approval of new substances or new uses or new levels of use of approved substances may be granted by the Administrator if:

(i) The substance has been previously approved by the Food and Drug Administration (FDA) for use in meat or meat food products as a food additive, color additive, or as a substance generally recognized as safe and is listed in Title 21 of the Code of Federal Regulations, Parts 73, 74, 81, 172, 173, 179, 182 and 184.

(ii) Its use is in compliance with applicable FDA requirements; and

(iii) The Administrator has determined that:

(A) The use of the substance will not render the product in which it is used adulterated or misbranded or otherwise not in compliance with the requirements of the Act; and

(B) Its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the stated technical effect as determined in specific cases.

(3) Whenever the Administrator determines that approval of a new substance or new use or new level of use of an approved substance should be granted in accordance with paragraph (a)(2) of this section, the Administrator shall issue a final rule amending the chart of substances in paragraph (c)(4) of this section to include the additional substance or new use of the substance, and any technical effect or change in level of use of the substance.

(4) No product shall bear or contain any substance which would render it adulterated or misbranded which is not approved in Part 318 or Part 319 of this subchapter or by the Administrator in specific cases.

(b) Requirements for the use of nitrite and sodium ascorbate or sodium erythorbate (isoascorbate) in bacon. Nitrates shall not be used in curing bacon.

(1) Pumped bacon: With respect to bacon injected with curing ingredients and massaged bacon: Sodium nitrite shall be used at 120 parts per million (PPM) ingoing or an equivalent amount of potassium nitrite shall be used (148 ppm ingoing); and 550 ppm of sodium ascorbate or sodium erythorbate (isoascorbate) shall be used. Sodium ascorbate or sodium erythorbate have a molecular weight of approximately 198. Hydrated forms of these substances shall be adjusted to attain the equivalent of 550 ppm of sodium ascorbate or sodium erythorbate.

(2) The Department shall collect samples of pumped bacon from producing plants and analyze them for the level of nitrosamines by the thermal energy analyzer (TEA). In the event that a TEA analysis indicates that a confirmable level of nitrosamines might be present, additional samples shall be collected and analyzed by gas chromatography. Presumptive positive results must be confirmed by mass spectrometry before being considered positive. If, during the interval required for the Department to analyze the confirmatory samples by gas chromatography and mass spectrometry, changes are made in processing procedures which are expected to result in no confirmable levels of nitrosamines in pumped bacon produced by these new procedures, an establishment may submit samples to USDA for analysis upon prior notification and arrangements with USDA. If, however, an establishment furnishes USDA

(§ 319.145 continued)

(c) If Italian sausage products are cooked or smoked, determination of compliance with the provisions of paragraphs (a) and (b) of this section shall be based on the uncooked or unsmoked product. The product before cooking or smoking shall contain no more than 3 percent water as specified in paragraph (b)(2) of this section. Product which is cooked shall be labeled with the word "cooked" in the product name, such as "Cooked Italian Sausage" or "Cooked Cured Italian Sausage." Product which is smoked shall be labeled with the word "smoked" in the product name, such as "Smoked Italian Sausage" or "Smoked Cured Italian Sausage." The words "cooked" and "smoked" shall be displayed on the product label in the same size and style of lettering as other words in the product name.

Subpart F-Uncooked, Smoked Sausage

§ 319.160 Smoked pork sausage.

"Smoked Pork Sausage" is pork sausage that is smoked with hardwood or other approved nonresinous materials. It may be seasoned with condimental substances as permitted in Part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

Subpart G-Cooked Sausage

§ 319.180 Frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, knockwurst and similar products.

(a) Frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, knockwurst and similar cooked sausages are comminuted, semi-solid sausages prepared from one or more kinds of raw skeletal muscle meat or raw skeletal muscle meat and raw or cooked poultry meat, and seasoned and cured, using one or more of the curing agents in accordance with § 318.7(c) of this chapter. They may or may not be smoked. The finished products shall not contain more than 30 percent fat. Water or ice, or both, may be used to facilitate chopping or mixing or to dissolve the curing ingredients but the sausage shall contain no more than 40 percent of a combination of fat and added water. These sausage products may contain only phosphates approved under Part 318 of this chapter. Such products may contain raw or cooked * poultry meat and/or Mechanically Separated (Kind of Poultry) without skin * * and without kidneys and sex glands used in accordance with § 381.174, * not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and Mechanically Separated (Species) used in accordance with § 319.6. Such poultry meat ingredients shall be designated in the ingredient statement on the label of such sausage in accordance with the provisions of § 381.118 of this chapter.

(b) Frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, knockwurst and similar cooked sausages that are labeled with the phrase "with byproducts" or "with variety meats" in the product name are comminuted, semi-solid sausages consisting of not less than 15 percent of

one or more kinds of raw skeletal muscle meat with raw meat byproducts, or not less than 15 percent of one or more kinds of raw skeletal muscle meat with raw meat byproducts and raw or cooked poultry products; and seasoned and cured, using one or more of the curing ingredients in accordance with § 318.7(c) of this chapter. They may or may not be smoked. Partially defatted pork fatty tissue or partially defatted beef fatty tissue, or a combination of both, may be used in an amount not exceeding 15 percent of the meat and meat byproducts or meat, meat byproducts, and poultry products ingredients. The finished products shall not contain more than 30 percent fat. Water or ice, or both, may be used to facilitate chopping or mixing or to dissolve the curing and seasoning ingredients, but the sausage shall contain no more than 40 percent of a combination of fat and added water. These sausage products may contain only phosphates approved under Part 318 of this chapter. These sausage products may contain poultry products * and/or Mechanically Separated (Kind of Poultry) used in accordance with * * § 381.174, individually or in combination, not in excess of 15 percent of * the total ingredients, excluding water, in the sausage, and may contain Mechanically Separated (Species) used in accordance with § 319.6. Such poultry products shall not contain kidneys or sex glands. The amount of poultry skin present in the sausage must not exceed the natural proportion of skin present on the whole carcass of the kind of poultry used in the sausage, as specified in § 381.117(d) of this chapter. The poultry products used in the sausage shall be designated in the ingredient statement on the label of such sausage in accordance with the provisions of § 381.118 of this chapter. Meat byproducts used in the sausage shall be designated individually in the ingredient statement on the label for such sausage in accordance with § 317.2 of this chapter.

(c) A cooked sausage as defined in paragraph (a) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst. When such sausage products are prepared with meat from a single species of cattle, sheep, swine, or goats they shall be labeled with the term designating the particular species in conjunction with the generic name; e.g., "Beef Frankfurter," and when such sausage products are prepared in part with Mechanically Separated (Species) in accordance with § 319.6, they shall be labeled in accordance with § 317.2(j)(13) of this subchapter.

(d) A cooked sausage as defined in paragraph (b) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst, in conjunction with the phrase "with byproducts" or "with variety meats" with such supplemental phrase shown in a prominent manner directly contiguous to the generic name and in the same color on an identical background.

(e) One or more of the binders and extenders as provided in § 318.7(c)(4) of this subchapter may be used in cooked sausage otherwise complying with paragraph (a) or (b) of this section. When any such substance is added to these products, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance.

(f) Cooked sausages shall not be labeled with terms such as "All Meat" or "All (Species)," or otherwise to indicate they do not contain nonmeat ingredients or are prepared only from meat.

(g) For the purposes of this section: Poultry meat means deboned chicken meat or turkey meat, or both, without skin or added fat; poultry products mean chicken or turkey, or chicken meat or turkey meat as defined in § 381.118 of this chapter, or poultry byproducts as defined in § 381.1 of this chapter; and meat byproducts (or variety meats) mean pork stomachs or snouts; beef, veal, lamb or goat tripe; beef, veal, lamb, goat or pork hearts, tongues, fat, lips, weasands and spleens; and partially defatted pork fatty tissue, or partially defatted beef fatty tissue.

§ 319.181 Cheesefurters and similar products.

"Cheesefurters" and similar products are products in casings which resemble frankfurters except that they contain sufficient cheese to give definite characteristics to the finished article. They may contain binders and extenders as provided in § 318.7(c)(4) of this subchapter. Limits on use as provided in § 318.7 are intended to be exclusive of the cheese constituent. When any such substance is added to these products, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance. These products shall contain no more than 40 percent of a combination of fat and added water, and no more than 30 percent fat and shall comply with the other provisions for cooked sausages that are in this subchapter.

§ 319.182 Braunschweiger and liver sausage or liverwurst.

(a) "Braunschweiger" is a cooked sausage made from fresh, cured and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, and/or veal livers computed on the weight of the fresh livers. It may also contain pork and/or beef fat. Mechanically Separated (Species) may be used in accordance with § 319.6. Binders and extenders may be used as permitted in § 319.140. The product may have a smoked taste characteristic, which may be imparted by use of smoked meats, smoke flavoring or smoking. If prepared from components of a single species, the product name may reflect the species, e.g., "Beef Braunschweiger. Braunschweiger may also be labeled as any of the following: "Braunschweiger--A Liver Sausage," "Braunschweiger--A Liverwurst," or "Braunschweiger (Liver Sausage)" or "Braunschweiger (Liverwurst)."

(b) "Liver Sausage" or "Liverwurst" is a cooked sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, veal, sheep, and/or goat livers computed on the weight of the fresh livers. It may also contain pork and/or beef byproducts. Mechanically Separated (Species) may be used in accordance with § 319.6. Binders and extenders may be used as permitted in § 319.140. If prepared from components of a single species, the product name may reflect that species, e.g., "Pork Liver Sausage."

Subpart H-[Reserved)

Subpart I - Semi-Dry Fermented Sausage [Reserved]

Subpart J-Dry Fermented Sausage [Reserved]

Subpart K - Luncheon Meat, Loaves and Jellied Products

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(§ 320.1(b) continued)

(6) Records of canning as required by Subpart G of this Subchapter A, 9 CFR Chapter III.

(7) Sample results and calculation results as required by processing procedures to destroy trichinae in § 318.10(c)(3)(iv) (Methods 5 and 6).

(8) Records of nutrition labeling as required by Subpart B, Part 317, of this subchapter.

(9) Records as required in § 318.23(b) and (c).

(10) Records of calcium content in meat derived from advanced meat/bone separation machinery and meat recovery systems as required by § 318.24 of this subchapter.

* (11) Records of all labeling, along with the product formulation and * processing procedures, as prescribed in § 317.4 and § 317.5. *

(Approved by the Office of Management and Budget under OMB #0583-0015)

§ 320.2 Place of maintenance of records.

Every person engaged in any business described in § 320.1 and required by this part to keep records shall maintain such records at the place where such business is conducted except that if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records shall be kept in a safe place at the prescribed location in accordance with good commercial practices.

§ 320.3 Record retention period.

(a) Every record required to be maintained under this part shall be retained for a period of 2 years after December 31 of the year in which the transaction to which the record relates has occurred and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such records under this part.

(b) Records of canning as required in Subpart G of this Subchapter A, 9 CFR Chapter III, shall be retained as required in § 318.307(e); except that records required by § 318.302(b) and (c) shall be retained as required by those sections.

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§ 327.14 Marking of products and labeling of immediate containers thereof for importation.

(a) Product which is offered for importation, and which is susceptible of marking, shall, whether or not enclosed in an immediate container, bear the name of the country of origin, preceded by the words "product of"; the establishment number assigned by the foreign meat inspection system and certified to the Program; and such other markings as are necessary for compliance with Part 316 of this subchapter. When such markings are imprints of stamps or brands made with branding ink, such ink shall be harmless and shall create permanent imprints. In case the name of the country of origin appears as part of an official mark of the national foreign government and such name is prominently and legibly displayed, the words "product of" may be omitted.

(b) In addition to the marking of products required under paragraph (a) of this section, the immediate container of any product offered for importation:

(1) Shall bear a label showing in accordance with § 317.2 of this subchapter all information required by that section (except that the establishment number assigned by the foreign meat inspection system and certified to the Program and the official inspection mark of the foreign meat inspection system shall be shown instead of the official inspection legend of the United States) and in addition the name of the country of origin preceded by the words "product of," immediately under the name or descriptive designation of the product as required by § 317.2: Provided, That such establishment number may be omitted from a label lithographed directly on a can if said number is lithographed or embossed elsewhere on the can; and

(2) Shall, if such immediate container is a sealed metal container, have the establishment number assigned by the foreign meat inspection authority and certified by the Program embossed or lithographed on the sealed metal container, and such establishment number shall not be covered or obscured by any label or other means.

(c) All marks and other labeling for use on or with immediate containers, as well as private brands on carcasses or parts of carcasses, shall be approved by the Food Safety and Inspection Service in accordance with part 317 of this subchapter before products bearing such marks, labeling, or brands will be entered into the United States. The marks of inspection of foreign systems embossed on metal containers or branded on carcasses or parts thereof need not be submitted to the Food Safety and Inspection Service for approval, and such marks of inspection put on stencils, box dies, labels, and brands may be used on such immediate containers as tierces, barrels, drums, boxes, crates, and large-size fiberboard containers of foreign products without such marks of inspection being submitted for approval, provided the markings made by such articles are applicable to the product and are not false or misleading.

§ 327.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.

(a) The outside container in which any immediate container of foreign product is shipped to the United States shall bear, in English, in a prominent and legible manner:

(1) The name or descriptive designation of the product in accordance with § 317.2 of this subchapter;
(2) The name of the country of origin; and
(3) The establishment number assigned by the foreign meat inspection system and certified to the Program.
(b) All labeling used with an outside container of foreign product must be approved in accordance with Part 317 of this subchapter.
(c) Except for product offered for entry from Canada, all outside containers of products which have been inspected and passed in accordance with this part shall be marked by a Program import inspector or under a Program import inspector's supervision with the official import meat inspection mark prescribed in § 327.26.

§ 327.16 Small importations for importer's own consumption; requirements.

Any product in a quantity of 50 pounds or less which was purchased by the importer outside the United States for his/her own consumption, is eligible to be imported into the United States from any country without compliance with the provisions in other sections of this part but subject to applicable requirements under other laws, including the regulations in Part 94 of this title. However, Program employees may inspect any product imported under this section to determine whether it is within the class eligible to be imported under this paragraph.

§ 327.17 Returned U.S. inspected and marked products.

U.S. inspected and passed and so marked products exported to and returned from foreign countries will be admitted into the United States without compliance with this part upon notification to and approval of the Deputy Administrator, International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250, in specific cases.

§ 327.18 Products offered for entry and entered to be handled and transported as domestic; exception.

(a) All products, after entry into the United States, shall be deemed and treated as domestic products and shall be subject to the applicable provisions of the Act and the regulations in this subchapter and the applicable requirements under the Federal Food, Drug and Cosmetic Act, except that products imported under § 327.16 are required to comply only with the requirements of that Act and § 327.16 of this subchapter.
(b) Products entered in accordance with this part may, subject to the provisions of Part 318 of this subchapter, be taken into official establishments and be mixed with or added to any product in such establishments which has been inspected and passed therein.
(c) Imported product which has been inspected, passed, and marked under this part may be transported in the course of importation or subsequently in commerce only upon compliance with Part 325 of this subchapter.

(i) The average PFF percentage of the five randomly selected sample units is equal to or greater than the applicable minimum PFF percentage required by § 319.104 or § 319.105 of this subchapter, or

(ii) The product is relabeled under the supervision of a program employee so that it conforms to the provisions of § 319.104 or § 319.105 of this subchapter.

(2) If product from a foreign establishment is subject to retention procedures under this section, the foreign establishment may be returned to normal monitoring procedures when:

(i) Ten consecutively presented lots of that cured pork product from that establishment have been sampled as provided in paragraph (c)(1) of this section and the average of each set of five sample units representing each lot have been found to be equal to or greater than the required minimum PFF percentage; and

(ii) The PFF percentage of each sample unit (50 in all) is above the Absolute Minimum PFF Percentage.

(3) If a country is subject to retention procedures under this section, the country shall be returned to normal monitoring procedures when:

(i) Twenty-five consecutively presented lots of cured pork product have been sampled as required in paragraph (c)(1) of this section and the average of each set of five sample units representing each lot have been found to be equal to or greater than the required minimum PFF percentage; and

(ii) The PFF percentage of each sample unit (125 in all) is above the Absolute Minimum PFF Percentage; and

(iii) Both of the PFF Standardized Averages for 36 consecutive lots are in the required percentage of the Normal distribution; and

(iv) Both of the PFF Standardized Averages for 100 consecutive lots are zero or higher.

(4) The sample units collected under retention procedures as provided in paragraph (c)(2) of this section will not be included in the PFF standardized averages for 36 and 100 consecutive lots.

(d) Adulterated and Misbranded Products. Products not meeting specified PFF requirements, determined according to procedures set forth in this section, may be deemed adulterated under section 1(m)(8) of the Act (21 U.S.C. 601(m)(8)) and misbranded under section 1(n) of the Act (21 U.S.C. 601(n)).

(e) Activities requiring additional inspectional supervision, such as relabeling, shall be at the importer's expense. In addition, if the importer wishes, he or she may have samples analyzed at an accredited laboratory.

§327.24 Appeals; how made.

Any appeal from a decision of any program employee shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, except as otherwise provided in the applicable rules of practice. * * * *

§ 327.25 Disposition procedures for product condemned or ordered destroyed under import inspection.

(a) Carcasses, parts thereof, meat and meat food products (other than rendered animal fats) that have been treated in accordance with the provisions of this section shall be considered denatured for the purposes

of the regulations in this part, except as otherwise provided in Part 314 of this subchapter for articles condemned at official establishments or at official import inspection establishments.

(1) The following agents are prescribed for denaturing carcasses, parts thereof, meat or meat food products which are affected with any condition that would result in their condemnation and disposal under Part 314 of this subchapter if they were at an official establishment or at an official import inspection establishment: Crude carbolic acid; cresylic disinfectant; a formula consisting of 1 part FD&C green No. 3 coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella, or other proprietary substance approved by the Administrator in specific cases. 1

(2) Meat may be denatured by dipping it in a solution of 0.0625 percent tannic acid, followed by immersion in a water bath, then dipping it in a solution of 0.0625 percent ferric acid; and except as provided in paragraph (3) and (5) of this section, the following agents are prescribed for denaturing other carcasses, parts thereof, meat and meat food products, for which denaturing is required by this part: FD&C green No. 3 coloring; FD&C blue No. 1 coloring; FD&C blue No. 2 coloring; finely powdered charcoal; or other proprietary substance approved by the Administrator in specific cases. Carcasses (other than viscera), parts thereof, cuts of meat, and unground pieces of meat darkened by charcoal or other black dyes shall be deemed to be denatured pursuant to this section only if they contain at least that degree of darkness depicted by diagram 1 of the Meat Denaturing Guide (MP Form 91). 2

(3) Tripe may be denatured by dipping it in a 6 percent solution of tannic acid for 1 minute followed by immersion in a water bath, then immersing it for 1 minute in a solution of 0.022 percent FD&C yellow No. 5 coloring.

(4) When meat, meat byproducts, or meat food products are in ground form, 4 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 5 mesh in the standards issued by the U.S. Bureau of Standards or 6 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 8 mesh in said Standards, uniformly incorporated with the product, may be used in lieu of the agents prescribed in paragraph (a)(2) of this section.

1/ Information as to approval of any proprietary denaturing substance may be obtained from the Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250.

2/ Copies of MP Form 91 may be obtained, without charge, by writing to the Administrative Operations Branch, Food Safety and Inspection Service, U.S. Department of Agriculture, 123 East Grant Street, Minneapolis, Minnesota 55403. Diagrams 2 and 3 of the Meat Denaturing Guide are for comparison purposes only. The Meat Denaturing Guide has been approved for incorporation by reference by the Director, Office of the Federal Register, and is on file at the Federal Register Library.

Subpart R-Cooperation With States and Territories; Certification of State and Territorial Programs as at Least Equal to Federal Program

Subpart S-Transportation; Exportation or Sale of Poultry or Poultry Products

Subpart T-Imported Poultry Products

not participate in, or intervene in (including the publishing or distribution of statements), any political campaign on behalf of (or in opposition to) any candidate for public office."

(5) The Administrator may withdraw or modify the exemption set forth in § 381.10(e)(1) for a particular establishment when he or she determines that such action is necessary to ensure food safety and public health. Before such action is taken, the owner or operator of the particular establishment shall be notified, in writing, of the reasons for the proposed action and shall be given an opportunity to respond, in writing, to the Administrator within 20 days after notification of the proposed action. The written notification shall be served on the owner or operator of the establishment in the manner prescribed in section 1.147(b) of the Department's Uniform Rules of Practice (7 CFR 1.147(b)). In those instances where there is conflict of any material fact, the owner or operator of the establishment, upon request, shall be afforded an opportunity for a hearing with respect to the disputed fact, in accordance with rules of practice which shall be adopted for the proceeding. However, such withdrawal or modification shall become effective pending final determination in the proceeding when the Administrator determines that an imminent threat to food safety or public health exists, and that such action is, therefore, necessary to protect the public health, interest or safety. Such withdrawal or modification shall be effective upon oral or written notification, whichever is earlier, to the owner or operator of the particular establishment as promptly as circumstances permit. In the event of oral notification, written confirmation shall be given to the owner or operator of the establishment as promptly as circumstances permit. This withdrawal or modification shall continue in effect pending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Administrator.

(6) The adulteration and misbranding provisions of the Act and the regulations apply to articles which are exempted from inspection under § 381.10(e).

§ 381.11 Exemptions based on religious dietary laws.

(a) Any person who slaughters, processes, or otherwise handles poultry or poultry products which have been or are to be processed as required by recognized religious dietary laws may apply for exemption from specific provisions of the Act or regulations which are in conflict with such religious dietary laws. Any person desiring such an exemption shall apply in writing to the Meat and Poultry Inspection Program, Food Safety and Inspection Service, Department of Agriculture, Washington, D.C. 20250, setting forth the specific provisions of the Act and the regulations from which exemption is sought and setting forth the provisions of the religious dietary laws in support of the requested exemption. In addition, the applicant for such an exemption shall submit a statement from the clerical official having jurisdiction over the enforcement of the religious dietary laws with respect to the poultry or poultry products involved, which identifies the requirements of such laws pertaining to the slaughter of the poultry and the processing or other handling of the poultry products involved, and certifies that such requirements are in conflict with specific provisions of the Act and regulations from which the exemption is sought.

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(b) The Administrator, upon a determination that an exemption should be granted, will grant such exemption to the extent necessary to avoid conflict with the religious requirements while still effectuating the purposes of the Act. He may impose such conditions as to sanitary standards, practices, and procedures in granting such exemption as he deems necessary to effectuate the purposes of the Act. Any person who processes poultry or poultry products under exemption from certain requirements as provided in this section shall be subject to all of the other applicable provisions of the Act and the regulations. Processing plants shall meet the sanitary requirements set forth in this part and unless exempted from inspection under the provisions of this subpart, shall be required to qualify for inspection and operate as official establishments. Slaughtered poultry which is prepared under an exemption authorizing the sale of nonevisceratedpoultry in commerce shall be individually identified with a label approved by the Administrator which identifies the clerical official under whose supervision the poultry was slaughtered.

§ 381.12 Effect of religious dietary laws exemptions on other persons.

Whenever a slaughterer or processor is granted an exemption under § 381.11 with respect to the slaughtering or processing of any poultry or poultry products under this part, under specified conditions, the sale, offer for sale, transportation and other handling in commerce by any person of such poultry and poultry products in accordance with such conditions is hereby authorized, except as restricted by the Act.

§ 381.13 Suspension or termination of exemptions.

(a) The Administrator may, by order, in accordance with the applicable rules of practice suspend or terminate any exemption under § 381.10(a) with respect to any person whenever he finds that such action will aid in effectuating the purposes of the Act. Failure to comply with the conditions of the exemption, including, but not limited to, failure to process poultry and poultry products under clean and sanitary conditions may result in termination of an exemption, in addition to any other penalties provided by law.

(b) Except as provided in § 381.10(c), the Administrator may extend the requirements of the Act to any establishment in any State or organized territory at which poultry products are processed for distribution solely within such jurisdiction if he determines in accordance with the provisions of subparagraph 5(c)(1) of the Act that the establishment is producing adulterated poultry products which would clearly endanger the public health.

§ 381.14 Inspection concerning purportedly exempted operations.

Inspectors of the Inspection Service are authorized to make inspections accordance with law to ascertain whether any of the provisions of the Act or the regulations applying to producers, retailers, or other persons purporting to be exempted from any requirements under this subpart have been violated.

§ 381.15 Exemption from definition of "poultry product" of certain human food products containing poultry.

The following articles contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry. Therefore said articles are exempted from the definition of "poultry product" and the requirements of the Act and the regulations applicable to poultry products, if they comply with the conditions specified in this section.

(a) Any human food product (in a consumer package) not provided for in paragraph (c) of this section, if:

(1) It contains less than 2 percent cooked poultry meat (deboned white * or dark poultry meat, or both) and/or "Mechanically Separated (Kind of * * Poultry)" as defined in § 381.173; *

(2) It contains less than 10 percent of cooked poultry skins, giblets, or fat, separately, and less than 10 percent of cooked poultry skins, * giblets, fat, and meats (as meat is limited in subparagraph (a)(1) of this * * section) or "Mechanically Separated (Kind of Poultry)" as defined in * * § 381.173, in any combination; *

(3) The poultry ingredients used in the product were prepared under inspection as defined in § 381.1, or were inspected under a foreign inspection system approved under § 381.196(b) and imported in compliance with the Act and the regulations;

(4) The immediate container of the product bears a label which shows the name of the product in accordance with this section; and (5) the product is not represented as a poultry product. The aforesaid percentages of ingredients shall be computed on the basis of the moist, deboned, cooked poultry in the ready-to-serve product when prepared according to the serving directions on the consumer package.

(b) Any human food product (in an institutional pack), not provided for in paragraph (c) of this section, if:

(1) It is prepared for sale only to institutional users, such as hotels, restaurants, and boardinghouses, for use as a soup base or flavoring;

(2) It contains less than 15 percent cooked poultry meat (deboned white * or dark poultry meat, or both) and/or "Mechanically Separated (Kind of * * Poultry)" as defined in § 381.173, computed on the basis of the moist * * deboned, cooked poultry meat and/or "Mechanically Separated (Kind of * * Poultry)" as defined in § 381.173 in such product; and *

(3) It complies with the provisions of paragraphs (a) (3), (4), and (5) of this section in all respects.

(c) Bouillon cubes, poultry broths, gravies, sauces, seasonings, and flavorings if:

* (1) They contain poultry meat and/or "Mechanically Separated (Kind of * * Poultry)" as defined in § 381.173 or poultry fat only in condimental * quantities; and

(2) They comply with the provisions of paragraphs (a) (3), (4), and (5) of this section in all respects; and (3) in the case of poultry broth, it will not be used in the processing of any poultry product in any official establishment.

(d) Fat capsules and sandwiches containing poultry products if they comply with the provisions of paragraphs (a) (3), (4), and (5) of this section in all respects.

§ 381.34 Financial interest of inspectors.

(a) No inspector shall inspect any poultry or poultry product in which he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner, or employee, or any person with whom he is negotiating or has any arrangement concerning prospective employment, is financially interested.

(b) All inspectors are subject to statutory restrictions with respect to political activities; e.g., 5 U.S.C. 7324 and 1502.

(c) Violation of the provisions of paragraph (a) of this section or the provisions of applicable statutes referenced in paragraph (b) of this section will constitute grounds for dismissal in the case of appointees and for revocation of licenses in the case of licensees.

(d) Inspectors are subject to all applicable provisions of law and regulations and instructions of the Department and the Food Safety and Inspection Service and other authority concerning employee responsibilities and conduct. The setting forth of certain prohibitions in this part in no way limits the applicability of such general or other regulations or instructions.

§ 381.35 Appeal inspections; how made.

Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: Provided, That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his immediate superior having jurisdiction over the subject matter of the appeal, and such superior shall determine whether the inspector's decision was correct. Review of such appeal determination, when required, shall be made by the immediate superior of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of $9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the * inspector pending completion of an appeal inspection. * * * *

Subpart G-Facilities for Inspection; Overtime and Holiday Service; Billing Establishments

§ 381.36 Facilities required.

(a) Inspector's Office. Office space, including, but not being limited to furnishings, light, heat, and janitor service, shall be provided rent free in the official establishment, for the use of Government personnel for official purposes. The room or space set apart for this purpose must meet the approval of the Inspection Service and be conveniently located, properly ventilated, and provided with lockers or file cabinets suitable for the protection and storage of supplies and with facilities suitable for inspectors to change clothing. At the discretion of the Administrator, small plants requiring the services of less than one full-time inspector need not furnish facilities for Program employees as prescribed in this

section, where adequate facilities exist in a nearby convenient location. Each official establishment shall provide commercial laundry service for inspectors' outer work clothing, or disposable outer work garments designed for one-time use, or uniform rental service garments which are laundered by the rental service.

(b) Facilities for ante-mortem inspection. Batteries, coops, or other facilities in which live poultry is presented for ante-mortem inspection shall be of such arrangement and construction, and shall be so placed with sufficient light provided so that the inspector can clearly see the birds to the extent needed to carry out an adequate inspection.

(c) Facilities for the Streamlined Inspection System (SIS). The following requirements for lines operating under SIS are in addition to the normal requirements to obtain a grant of inspection. The requirements for SIS in § 381.76(b) also apply.

(1) The following provisions shall apply to every inspection station:

(i) The conveyor line shall be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (c)(1)(iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 4 feet along the conveyor line for the inspector, and 4 feet for the establishment helper. A total of at least 8 feet along the conveyor line shall be supplied for one inspection station and 16 feet for two-inspection stations.

(iii) Selectors or "kickouts" shall be installed in establishments with two inspection stations on a line so each inspector will receive birds on 12-inch centers with no intervening birds to impede inspector. The selector must move the bird to the edge of the trough for the inspector and establishment helper. The selectors must be smooth, steady, and consistent in moving the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid swinging when entering the inspection station.

(iv) Each inspector's station shall meet the requirements specified in § 381.53. The station shall have a platform that is slip-resistant and can be safely accessed by the inspector. The platform shall be designed so that it can be easily and rapidly adjusted for a minimum of 14 inches vertically while standing on the platform. The platform shall be a minimum length of 4 feet and have a minimum width of 2 feet; the platform shall be designed with a 42-inch high rail on the back side and with 1/2-inch foot bumpers and both sides and front to allow safe working conditions. The platform must have a safe lift mechanism and be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

(v) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(vi) A trough or other facilities complying with section 381.53(g)(4) of this Part shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between the suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splash.

(c)(1) The information panel is that part of a label that is the first surface to the right of the principal display panel as observed by an individual facing the principal display panel, with the following exceptions:

(i) If the first surface to the right of the principal display panel is too small to accommodate the required information or is otherwise unusable label space, e.g., folded flaps, tear strips, opening flaps, heat-sealed flaps, the next panel to the right of this part of the label may be used.

(ii) If the package has one or more alternate principal display panels, the information panel is to the right of any principal display panel.

(iii) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(2)(i) Except as otherwise permitted in this part, all information required to appear on the principal display panel or permitted to appear on the information panel shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as otherwise prescribed in this part, any vignettes, designs, and any other nonmandatory information shall not be considered. If there is insufficient space for all required information to appear on a single panel, it may be divided between the principal display panel and the information panel, provided that the information required by any given provision of this part, such as the ingredients statement, is not divided and appears on the same panel.

(ii) All information appearing on the information panel pursuant to this section shall appear in one place without intervening material, such as designs or vignettes.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars.

* § 381.117 Name of product and other labeling. *

(a) The label shall show the name of the product, which, in the case of a poultry product which purports to be or is represented as a product for which a definition and standard of identity or composition is prescribed in Subpart P, shall be the name of the food specified in the standard, and in the case of any other poultry product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation.

(b) The name of the product required to be shown on labels for fresh or frozen raw whole carcasses of poultry shall be in either of the following forms: The name of the kind (such as chicken, turkey, or duck) preceded by the qualifying term "young" or "mature" or "old", whichever is appropriate; or the appropriate class name as described in § 381.170(a). The name of the kind may be used in addition to the class name, but the name of the kind alone without the qualifying age or class term is not acceptable as the name of the product, except that the name "chicken" may be used without such qualification with respect to a ready-to-cook pack of fresh or frozen cut-up young chickens, or a half of a young chicken, and the name "duckling" may be

used without such qualification With respect to a ready-to-cook pack of fresh or frozen young ducks. The class name may be appropriately modified by changing the word form, such as using the term "roasting chicken", rather than "roaster." The appropriate names for cut-up parts are set forth in § 381.170 (b). When naming parts cut from young poultry, the identity of both the kind of poultry and the name of the part shall be included in the product name. The product name for parts or portions cut from mature poultry shall include, along with the part or portion name, the class name or the qualifying term "mature." The name of the product for cooked or heat processed poultry products shall include the kind name of the poultry from which the product was prepared but need not include the class name or the qualifying term "mature."

(c) Poultry products containing light and dark chicken or turkey meat in quantities other than the natural proportions, as indicated in Table 1 in this paragraph, must have a qualifying statement in conjunction with the name of the product indicating, as shown in Table 1, the types of meat actually used, except that when the product contains less than 10 percent cooked deboned poultry meat or is processed in such a manner that the character of the light and dark meat is not distinguishable, the qualifying statement will not be required, unless the product bears a label referring to the light or dark meat content. In the latter case, the qualifying statement is required if the light and dark meat are not present in natural proportions. The qualifying statement must be in type at least one-half the size and of equal boldness as the name of the product; e.g., Boned Turkey (Dark Meat).

Table 1

Label terminology	Percent light meat	Percent dark meat
Natural proportions	50-65	50-35.
Light or white meat	100	0.
Dark meat	0	100.
Light and dark meat	51-65	49-35.
Dark and light meat	35-49	65-51.
Mostly white meat	66 or more	34 or less.
Mostly dark meat	34 or less	66 or more.

(d) Boneless poultry products shall be labeled in a manner that accurately describes their actual form and composition. The product name shall specify the form of the product (e.g., emulsified, finely chopped, etc.), and the kind name of the poultry, and if the product does not consist of natural proportions of skin and fat, as they occur in the whole carcass, shall also include terminology that describes the actual composition. If the product is cooked, it shall be 80 labeled. For the purpose of this paragraph, natural proportions of skin, as found on a whole chicken or turkey carcass, will be considered to be as follows:

	Raw	Cooked
	Percent	
Chicken	20	25
Turkey	15	20

Boneless poultry product shall not have a bone solids content of more than 1 percent, calculated on a weight basis.

* (e) On the label of any "Mechanically Separated (Kind of Poultry)" described in § 381.173, the name of such product shall be followed immediately by the phrase: "with excess skin" unless such product is made from poultry product that does not include skin in excess of the natural proportion of skin present on the whole carcass, as specified in paragraph (d) of this section. Appropriate terminology on the label shall indicate if heat treatment has been used in the preparation of the product. The labeling information described in this paragraph shall be identified on the label before the product leaves the establishment at which it is manufactured. *

§ 381.118 Ingredients statement.

(a)(1) The label shall show a statement of the ingredients in the poultry product if the product is fabricated from two or more ingredients. Such ingredients shall be listed by their common or usual names in the order of their descending proportions, except as prescribed in paragraph (a)(2) of this section.

(2)(i) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: Provided, That such ingredients are listed by their common or usual names at the end of the ingredients statement and preceded by a quantifying statement, such as "Contains _____ percent or less of _____," or "Less than _____ percent of _____." The percentage of the ingredient(s) shall be filled in with a threshold level of 2 percent, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying statement applies may be present in an amount greater than the stated threshold. Such a quantifying statement may also be utilized when an ingredients statement contains a listing of ingredients by individual components. Each component listing may utilize the required quantifying statement at the end of each component ingredients listing.

(ii) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with § 381.147(f)(4) and subpart P of this Part, and does not exceed the amount shown in the quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

(b) For the purpose of this paragraph, the term "chicken meat," unless modified by an appropriate adjective, is construed to mean deboned white and dark meat; whereas the term "chicken" may include other edible parts such as skin and fat not in excess of their natural proportions, in addition to the chicken meat. If the term "chicken meat" is listed and the product also contains skin, giblets, or fat, it is necessary to list each such ingredient. Similar principles shall be followed in listing ingredients of poultry products processed from other kinds of poultry.

(c) The terms spice, natural flavor, natural flavoring, flavor or flavoring may be used in the following manner:

(1) The term "spice" means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(2) The term "natural flavor," "natural flavoring," "flavor" or "flavoring" means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portions of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powdered onion, powdered garlic, and powdered celery.

(i) Natural flavor, natural flavoring, flavor or flavoring as described in paragraph (c)(1) and (2) of this section, which are also colors shall be designated as "natural flavor and coloring," "natural flavoring and coloring," "flavor and coloring" or "flavoring and coloring" unless designated by their common or usual name.

(ii) Any ingredient not designated in paragraph (c)(1) and (2) of this section whose function is flavoring, either in whole or in part, must be designated by its common or usual name. Those ingredients which are of livestock or poultry origin must be designated by names that include the species and livestock and poultry tissues from which the ingredients are derived.

(d) On containers of frozen dinners, entrees, and pizzas, and similarly packaged products in cartons, the ingredient statement may be placed on the front riser panel: Provided, That the words "see ingredients," followed immediately by an arrow pointing to the front riser panel, are placed on the principal display panel immediately above the location of such statement, without intervening printing or designs.

(e) The ingredients statement may be placed on the information panel, except as otherwise permitted in this subchapter.

§ 381.119 Declaration of artificial flavoring or coloring.

(a) When an artificial smoke flavoring or a smoke flavoring is added as an ingredient in the formula of any poultry product, there shall appear on the label, in prominent letters and contiguous to the name of the product, a statement such as "Artificial Smoke Flavoring Added" or "Smoke Flavoring Added," as applicable, and the ingredient statement shall identify any artificial smoke flavoring or smoke flavoring added as an ingredient in the formula of the poultry product.

information necessary to identify the product, and shall furnish a copy of the authorization record upon request. Before being offered for sale at a retail entity, such product shall be relabeled.

(c) A calendar date may be shown on labeling when declared in accordance with the provisions of this paragraph:

(1) The calendar date shall express the month of the year and the day of the month for all products and also the year in the case of products hermetically sealed in metal or glass containers, dried or frozen products, or any other products that the Administrator finds should be labeled with the year because the distribution and marketing practices with respect to such products may cause a label without a year identification to be misleading.

(2) Immediately adjacent to the calendar date shall be a phrase explaining the meaning of such date in terms of "packing" date, "sell by" date, or "use before" date, with or without a further qualifying phrase, e.g., "For Maximum Freshness" or "For Best Quality", and such phrases shall be approved by the Administrator as prescribed in § 381.132.

(d) When sodium alginate, calcium carbonate, lactic acid, and calcium lactate are used together in a dry binding matrix in ground and formed poultry products, as permitted in § 381.147 of this subchapter, there shall appear on the label contiguous to the product name, a statement to indicate the use of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.

§ 381.130 False or misleading labeling or containers; orders to withhold from use.

If the Administrator has reason to believe that any marking or other labeling or the size or form of any container in use or proposed for use with respect to any article subject to the Act is false or misleading in any particular, he may direct that the use of the article be withheld unless it is modified in such manner as the Administrator may prescribe so that it will not be false or misleading. If the person using or proposing to use the labeling or container does not accept the determination of the Administrator, he may request a hearing, but the use of the labeling or container shall, if the Administrator so directs, be withheld pending hearing and final determination by the Secretary in accordance with applicable rules of practice. Any such determination with respect to the matter by the Secretary shall be conclusive unless, within 30 days after the receipt of notice of such final determination, the person adversely affected thereby appeals to the U.S. Court of Appeals for the Circuit in which he has his principal place of business, or to the U.S. Court of Appeals for the District of Columbia Circuit. The provisions of section 204 of the Packers and Stockyards Act of 1921, as amended, shall be applicable to appeals taken under this section.

§ 381.131 Preparation of labeling or other devices bearing official inspection marks without advance approval prohibited; exceptions.

(a) Except for the purposes of preparing and submitting a sample or samples of the same to the Administrator for approval, no brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any marking device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, without the written authority therefor of the Administrator. However,

(§ 381.131(b) continued)

(1) The certificate is a Food Safety and Inspection Service form for signature by a Program employee and the official establishment ordering the marking device, bearing a certificate serial number and a letterhead and the seal of the United States Department of Agriculture. The certificate authorizes the making of only the devices of the type and quantity listed on the certificate.

(2) After signing the certificate, the Program employee and the establishment shall each keep a copy, and the remaining two copies shall be given to the marking device manufacturer.

(3) The manufacturer of the marking devices shall engrave or otherwise mark each marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer the number of each marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy with the marking devices to the Program employee whose name and address are given on the certificate as the recipient.

(4) In order that all such marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such marking device that does not bear an identifying number, or, under the direction of the inspector-in-charge, mark such marking device with a permanent identifying number.

(The recordkeeping requirements under this section have been approved by the Office of Management and Budget under OMB # 0583-0015.)

* § 381.132 Labeling approval. *

* (a) No final labeling shall be used on any product unless the sketch *
* labeling of such final labeling has been submitted for approval to the *
* Food Labeling Division, Regulatory Programs, Food Safety and Inspection *
* Service, and approved by such division, accompanied by FSIS Form, Applica- *
* tion for Approval of Labels, Marking, and Devices, except for generically *
* approved labeling authorized for use in § 381.133(b)(2)-(9). The manage- *
* ment of the official establishment or establishment certified under a *
* foreign inspection system, in accordance with subpart T of this part, must *
* maintain a copy of all labeling used, along with the product formulation *
* and processing procedure, in accordance with subpart Q of this part. Such *
* records shall be made available to any duly authorized representative of *
* the Secretary upon request. *
* (b) The Food Labeling Division shall permit submission for approval *
* of only sketch labeling, as defined in § 381.132(d), for all products, *
* except as provided in § 381.133(b)(2)-(9) and except for temporary use of *
* final labeling as prescribed in paragraph (f) of this section. *
* (c) All labeling required to be submitted for approval as set forth *
* in § 381.132(b) shall be submitted in duplicate to the Food Labeling *
* Division, Regulatory Programs, Food Safety and Inspection Service, U.S. *
* Department of Agriculture, Washington, DC 20250. A parent company for a *
* corporation may submit only one labeling application (in duplicate) for a *
* product produced in other establishments that are owned by the corporation. *
* (d) "Sketch" labeling is a printer's proof or equivalent which *
* clearly shows all labeling features, size, location, and indication of *
* final color, as specified in subpart N of this part. FSIS will accept *
* sketches that are hand drawn, computer generated or other reasonable *

facsimiles that clearly reflect and project the final version of the labeling. Indication of final color may be met by: submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with the sketch of previously approved final labeling that indicates the final colors.

(e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in § 381.132(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in § 381.133(b)(9).

(f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days under the following conditions:

(i) The proposed labeling would not misrepresent the product;

(ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;

(iii) Denial of the request would create undue economic hardship; and

(iv) An unfair competitive advantage would not result from the granting of the temporary approval.

(2) Extensions of temporary approvals may also be granted by the Food Labeling Division, provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

§ 381.133 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with subpart T of this part, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accord with this section and shows all mandatory features in a prominent manner as required in subpart N of this part, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service shall select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with subpart T of this part, as required in § 381.132, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in § 381.233.

(b) Generically approved labeling is labeling which complies with the following:

(1) Labeling for a product which has a product standard as specified in subpart 381 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled in a foreign language;

(2) Labeling for single-ingredient products (such as chicken legs or turkey breasts) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(3) Labeling for containers of products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;

(4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 381.127;

(5) Labeling for products not intended for human food, provided they comply with §§ 381.152(c) and 381.193, and labeling for poultry heads and feet for export for processing as human food if they comply with § 381.190(b);

(6) Poultry inspection legends, which comply with subpart M of this part;

(7) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature;

(8) Labeling for consumer test products not intended for sale; and

(9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) The substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement, e.g., "lb." for "pound," or "oz." for "ounce," or of the word "pound" for "lb." or "ounce" for "oz.";

(iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words "prepared for" or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

(iv) Wrappers or other covers bearing pictorial designs, emblematic designs or illustrations, e.g., floral arrangements, illustrations of animals, fireworks, etc. are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

(viii) Any change in the net weight, provided that the size of the net weight statement complies with § 381.121;

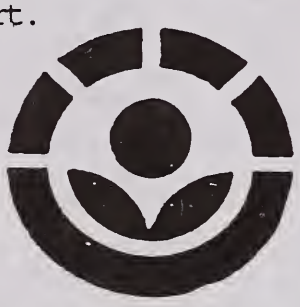
* (ix) The addition, deletion, or amendment of recipe suggestions for the product;
* (x) Any change in punctuation;
* (xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the Food Labeling Division, Regulatory Programs;
* (xii) The addition or deletion of open dating information;
* (xiii) A change in the type of packaging material on which the label is printed;
* (xiv) Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;
* (xv) The deletion of the word "new" on new product labeling;
* (xvi) The addition, deletion, or amendment of special handling statements, provided that the change is consistent with § 381.125(a);
* (xvii) The addition of safe handling instructions as required by § 381.125(b);
* (xviii) Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in § 381.147 and subpart P of this part;
* (xix) Changes in the color of the labeling, provided that sufficient contrast and legibility remain;
* (xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package;
* (xxi) The addition, deletion, or substitution of the official USDA poultry grade shield;
* (xxii) A change in the establishment number by a corporation or parent company for an establishment under its ownership;
* (xxiii) Changes in nutrition labeling that only involve quantitative adjustments to the nutrition labeling information, except for serving sizes, provided the nutrition labeling information maintains its accuracy and consistency;
* (xxiv) Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information;
* (xxv) The addition or deletion of a direct translation of the English language into a foreign language for products marked "for export only"; and
* (xxvi) The addition of a descriptive term as required by § 381.129(b)(6).

* § 381.134 Requirement of formulas. *

Copies of each label submitted for approval, shall when the Administrator requires in any specific case, be accompanied by a statement showing, by their common or usual names, the kinds and percentages of the ingredients comprising the poultry product and by a statement indicating the method or preparation of the product with respect to which the label is to be used. Approximate percentages may be given in cases where the percentages of ingredients may vary from time to time, if the limits of variation are stated.

§ 381.135 Irradiated poultry product.

(a) The labeling of packages of poultry product irradiated in conformance with § 381.147(f)(4) of this part must bear the following logo along with a statement such as, "Treated with radiation" or "Treated by irradiation," in addition to all other labeling requirements of this subpart. The logo must be placed prominently and conspicuously in conjunction with the required statement and be colored green. The statement must appear as a qualifier contiguous to the product name and in letters of the same style, color, and type as the product name. Letters used for the qualifying statement shall be no less than one-third the size of the largest letter in the product name. Any labeling bearing the logo and any wording of explanation with respect to this logo must be proved as required by subparts M and N of this part.



(b) The product label must bear the handling statement "Keep Refrigerated" or "Keep Frozen," as appropriate, in conformance with § 381.125 of this Subpart.

(c) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the above stated requirements. Such statements must not be false or misleading.

§ 381.136 Affixing of official identification.

(a) No official inspection legend or any abbreviation or other simulation thereof may be affixed to or placed on or caused to be affixed to or placed on any poultry product or container thereof, except by an inspector or under the supervision of an inspector or other person authorized by the Administrator, and no container bearing any such legend shall be filled except under such supervision.

(b) No official inspection legend shall be used on any poultry product or other article which does not qualify for such mark under the regulations.

§ 381.137 Evidence of labeling and devices approval.

No inspector shall authorize the use of any device bearing any * official inspection legend unless he or she has on file evidence that such * device has been approved in accordance with the provisions of this subpart.

§ 381.138 Unauthorized use or disposition of approved labeling or devices.

(a) Labeling and devices approved for use pursuant to § 381.115 shall be used only for the purpose for which approved, and shall not be disposed of from the official establishment for which approved except with written approval of the Administrator. Any unauthorized use or disposition of approved labeling or devices bearing official inspection marks is prohibited and may result in cancellation of the approval.

(b) Labeling and containers bearing any official inspection marks, with or without the official establishment number, may be transported from one official establishment to any other official establishment, only if such shipments are made with the prior authorization of the inspector in charge at point of origin, who will notify the inspector in charge at destination concerning the date of shipment, quantity, and type of labeling material involved. Approved labeling and containers may be moved without restriction under this part between official establishments operated by the same person if such labeling and containers are approved for use at all such establishments. No such material shall be used at the establishment to which it is shipped unless such use conforms with the requirements of this subpart.

§ 381.139 Removal of official identifications.

(a) Every person who receives any poultry product in containers which bear any official inspection legend shall remove or deface such legend or destroy the containers upon removal of such articles from the containers.
(b) No person shall alter, detach, deface, or destroy any official identifications prescribed in Subpart M that were applied pursuant to the regulations, unless he is authorized to do so by an inspector or this section; and no person shall fail to use any such official identification when required by this part.

§ 381.140 Relabeling poultry products.

When it is claimed by the operator of an official establishment that some of its labeled poultry product, which has been transported to a location other than an official establishment, is in need of relabeling because the labeling has become mutilated or damaged, or for some other reason needs relabeling, the requests for relabeling the poultry product shall be sent to the Administrator and accompanied with a statement of the reasons therefor and the quantity of labeling required. Labeling material intended for relabeling inspected and passed product shall not be transported from an official establishment until permission has been received from the Administrator. The relabeling of inspected and passed product with official labels shall be done under the supervision of an inspector pursuant to the regulations in Part 362 of this chapter. The establishment shall reimburse the Inspection Service for any cost involved in supervising the relabeling of such product as provided in said regulations.

* § 381.141 [Reserved] *

§ 381.143 [Reserved]

§ 381.144 Packaging materials.

(a) Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for the intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA).

(b) Packaging materials entering the official establishment must be accompanied or covered by a guaranty, or statement of assurance, from the packaging supplier under whose brand name and firm name the material is marketed to the official establishment. The guaranty shall state that the material's intended use complies with the FFDCA and all applicable food additive regulations. The guaranty must identify the material, e.g., by the distinguishing brand name or code designation appearing on the packaging material shipping container; must specify the applicable conditions of use, including temperature limits and other pertinent limits specified under the FFDCA and food additive regulations; and must be signed by an authorized official of the supplying firm. The guaranty may be limited to a specific shipment of an article, in which case it may be part of or attached to the invoice covering such shipment, or it may be general and continuing, in which case, in its application to any article or other shipment of an article, it shall be considered to have been given at the date such article was shipped by the person who gives the guaranty. Guaranties consistent with the Food and Drug Administration's regulations regarding such guaranties (21 CFR 7.12 and 7.13) will be acceptable. The management of the establishment must maintain a file containing guaranties for all food contact packaging materials in the establishment. The file shall be made available to Program inspectors or other Department officials upon request. While in the official establishment, the identity of all packaging materials must be traceable to the applicable guaranty.

(c) The guaranty by the packaging supplier will be accepted by Program inspectors to establish that the use of material complies with the FFDCA and all applicable food additive regulations.

(d) The Department will monitor the use of packaging materials in official establishments to assure that the requirements of paragraph (a) of this section are met, and may question the basis for any guaranty described under paragraph (b) of this section. Official establishments and packaging suppliers providing written guaranties to those official establishments will be permitted an opportunity to provide information to designated Department officials as needed to verify the basis for any such guaranty. The required information will include, but is not limited to, manufacturing firm's name, trade name or code designation for the material, complete chemical composition, and use. Selection of a material for review does not in itself affect a material's acceptability. Materials may continue to be used during the review period. However, if information requested from the supplier is not provided within the time indicated in the request--a minimum of 30 days -- any applicable guaranty shall cease to be effective and approval to continue using the specified packaging material in official establishments may be denied. The Administrator may extend this time where reasonable grounds for extension are shown, as, for example, where data must be obtained from suppliers.

Class of substance	Substance	Purpose	Products	Amount
Antifoaming Agent,	Methyl polysilicone.	To retard foaming.	Soups.	10 ppm.
			Rendered fats.	10 ppm.
			Curing pickle.	50 ppm.
* * * * * * * * * * * Antimicrobial agents.	Trisodium phosphate.	To reduce microbial levels.	Raw, chilled poultry carcasses.	8 to 12 percent; solution to be maintained at 45°F. to 55°F. and applied by spraying or dipping carcasses for up to 15 seconds in accordance with 21 CFR. 182.1778. * * * * * * * * * * *
Antioxidants and oxygen interceptors.	BHA (butylated hydroxyanisole).	To retard rancidity.	Various.	0.01 percent based on fat content. (0.02 percent in combination with any other antioxidant listed in this table based on fat content.)
	BHT (butylated hydroxytoluene).	do	do	Do.
	Propyl gallate.	do	do	0.01 percent based on fat content. (0.02 percent in combination with any other antioxidant listed in this table, except TBHQ, based on fat content.)
	TBHQ (tertiary butylhydroquinone).	do	do	0.01 percent based on fat content. (0.02 percent in combination only with BHA and/or BHT based on fat content.)

Class of substance	Substance	Purpose	Products	Amount
	Tocopherols.	do	do	0.03 percent based on fat content. (0.02 percent in combination with any other antioxidant listed in this table, except TBHQ, based on fat content.)
Binders and extenders.	A mixture of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.	To bind poultry pieces.	Ground and formed raw or cooked poultry pieces.	Sodium alginate not more than 0.8%, calcium carbonate not more than 0.15% lactic acid and clacium lactate, in combination, not more than 0.6% of product formulation. Added mixture may not exceed 1.55% of product at formulation. The mixture must be added in dry form.
	Algin.	To extend and stabilize product.	Various.	Sufficient for purpose.
	Carrageenan	do	do	Do.
	Carboxymethyl cellulose (cellulose gum).	do	do	Do.
	Enzyme (rennet) treated calcium reduced dried skim milk and calcium lactate.	To bind and extend product.	Various.	Sufficient for purpose. (Calcium lactate required at rate of 10 percent of binder.)
	Enzyme (rennet) treated sodium caseinate and calcium lactate.	do	do	Sufficient for purpose. (Calcium lactate required at rate of 25 percent of binder.)

*U.S. G.P.O.:1996-404-301:40009/FSIS

Class of substance	Substance	Purpose	Products	Amount
	Sodium pyrophosphate.	do	do	Do.
	Sodium acid pyrophosphate.	do	do	Do.
	Dipotassium phosphate.	do	do	Do.
	Monopotassium phosphate.	do	do	Do.
	Potassium tripolyphosphate.	do	do	Do.
	Potassium pyrophosphate.	do	do	Do.
	Tricalcium phosphate.	To preserve product color during dehydration process.	Mechanically deboned chicken to be dehydrated.	Not to exceed 2 percent of the weight of the mechanically deboned chicken prior to dehydration, in accordance with 21 CFR 182.1217.
* * * * * * * * * *	Sodium citrate buffered with citric acid to a pH of 5.6.	To inhibit the growth of microorganisms and and retain product flavor during storage.	Cured and uncured, processed whole-muscle food products, e.g., chicken breasts.	Not to exceed 1.3 percent of the formulation weight of the product in accordance with 21 CFR 184.1751.
Poultry scald agents; must be removed by subsequent cleaning operations.	Alpha-hydro-omega-hydroxypoly (oxyethylene) poly (oxypropylene) (minimum 15 moles) poly (oxyethylene) block copolymer (polyoxamer).	To remove feathers.	Poultry carcasses	Not to exceed 0.05% by weight in scald water.
	Dimethylpolysiloxane.	do	do	Sufficient for purpose.

Class of substance	Substance	Purpose	Products	Amount
	Dioctyl sodium sulfosuccinate.	do	do	Do.
	Dipotassium phosphate.	do	do	Do.
	Ethylenediamine-tetraacetic acid (sodium salts).	do	do	Do.
	Lime (calcium oxide, calcium hydroxide).	do	do	Do.
	Polyoxyethylene (20) sorbitan monooleate.	do	do	Not to exceed 0.0175% in scald water.
	Potassium hydroxide.	do	do	Sufficient for purpose.
	Propylene glycol.	do	do	Do.
	Sodium acid phosphate.	do	do	Do.
	Sodium bicarbonate.	do	do	Do.
	Sodium carbonate.	do	do	Do.
	Sodium dodecylbenzene-sulfonate.	do	do	Do.
	Sodium-2-ethyhexyl sulfate.	do	do	Do.
	Sodium hexametaphosphate.	do	do	Do.
	Sodium hydroxide.	do	do	Do.

*U.S. G.P.O.:1996-404-301:40004/FSIS

(12) "Quarters" consist of the entire eviscerated poultry carcass, which has been cut into four equal parts, but excluding the neck.

(13) "Breast quarter" consists of half a breast with the wing and a portion of the back attached.

(14) "Breast quarter without wing" consists of a front quarter of a poultry carcass, from which the wing has been removed.

(15) "Leg quarter" consists of a poultry thigh and drumstick, with a portion of the back attached.

(16) "Thigh with back portion" consists of a poultry thigh with back portion attached.

(17) "Legs with pelvic bone" consists of a poultry leg with adhering meat and skin and pelvic bone.

(18) "Wing drummette" consists of the humerus of a poultry wing with adhering skin and meat attached.

(19) "Wing portion" consists of a poultry wing except that the drummette has been removed.

(20) "Cutup Poultry" is any cutup or disjointed portion of poultry or any edible part thereof, as described in this section.

(21) "Giblets" consist of approximately equal numbers of hearts, gizzards, and livers, as determined on a count basis.

§ 381.171 Definition and standard for "Turkey Ham."

(a) "Turkey Ham" shall be fabricated from boneless, turkey thigh meat with skin and the surface fat attached to the skin removed. The thighs shall be that cut of poultry described in § 381.170(b)(5) of this Part.

(b) The product may or may not be smoked, and shall be cured using one or more of the approved curing agents as provided in § 381.147(f) of this Part. The product may also contain cure accelerators, phosphates, and flavoring agents as provided in § 381.147(f) of this Part; common salt, sugars, spices, spice extractives, dehydrated garlic, and dehydrated onions; and water for purpose of dissolving and dispersing the substances specified above.

(c) The cooked finished product weight shall be no more than the original weight of the turkey thigh meat used prior to curing.

(d) The product name on the label shall show the word "Turkey" in the same size, style, color, and with the same background as the word "Ham" and shall precede and be adjacent to it.

(e) The product name shall be qualified with the statement "Cured Turkey Thigh Meat." The qualifying statement shall be contiguous to the product name, without intervening type or designs, shall be not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and with the same background as the product name.

(f) If the product is fabricated from pieces of turkey thigh meat that result from the cutting through the muscle (as opposed the whole thighs intact or whole thighs with some incidental separation of muscle tissue during removal of the bone), the product name shall be further qualified by a descriptive statement. The product name of product fabricated from such pieces of turkey thigh meat equivalent in size to a one-half inch cube or greater shall be further qualified to specify that the product is "Chunked and Formed." The product name of product fabricated from such pieces of turkey thigh meat smaller than the equivalent of a one-half inch cube shall

be further qualified to specify that the product is "Ground and Formed" or "Chopped and Formed" as appropriate. The qualifying statement shall immediately follow and be contiguous to the statement required in paragraph (e) of this section, and shall be not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and with the same background as the product name.

§ 381.173 Mechanically Separated (Kind of Poultry).

(a) "Mechanically Separated (Kind of Poultry)" is any product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle and other tissue of poultry carcasses and parts of carcasses that has a paste-like form and consistency, that may or may not contain skin with attached fat and meeting the other provisions of this section. Examples of such product are "Mechanically Separated Chicken" and "Mechanically Separated Turkey."

(b) "Mechanically Separated (Kind of Poultry)" shall not have a bone solids content of more than 1 percent. At least 98 percent of the bone particles present in "Mechanically Separated (Kind of Poultry)" shall have a maximum size no greater than 1.5 mm (millimeter) in their greatest dimension and there shall be no bone particles larger than 2.0 mm in their greatest dimension.

(c) "Mechanically Separated (Kind of Poultry)" shall not have a calcium content exceeding 0.235 percent when made from mature chickens or from turkeys as defined in § 381.170(a)(1)(vi) and (vii) and (a)(2), respectively, or 0.175 percent when made from other poultry, based on the weight of product that has not been heat treated, as a measure of a bone solids content of not more than 1 percent.

(d) "Mechanically Separated (Kind of Poultry)" may be used in the formulation of poultry products in accordance with § 381.174 and meat food products in accordance with subchapter A of this chapter.

(e) Product resulting from the mechanical separation process that fails to meet the bone particle size or calcium content requirements for "Mechanically Separated (Kind of Poultry)" shall be used only in producing poultry extractives, including fats, stocks, and broths and labeled as "Mechanically Separated (Kind of Poultry) for Further Processing."

§ 381.174 Limitations with respect to use of Mechanically Separated (Kind of Poultry).

(a) A poultry product required to be prepared from a particular kind of poultry (e.g., chicken) shall not contain "Mechanically Separated (Kind of Poultry)" described in § 381.173, that is made from any other kind of poultry (e.g., Mechanically Separated Turkey).

(b) "Mechanically Separated (Kind of Poultry)" described in § 381.173 may be used in the formulation of any poultry or meat food product, provided such use conforms with any applicable requirements of the definitions and standards of identity or composition in this subchapter or part 319 of this chapter, and provided that it is identified as "Mechanically Separated (Kind of Poultry)."

§ 381.175 Records required to be kept.

(a) Every person within any of the classes specified in subparagraph (1), (2), or (3) of this paragraph is required by the Act to keep such records as are properly necessary for the effective enforcement of the Act:
(1) Any person that engages in the business of slaughtering any poultry or processing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any poultry, for commerce, for use as human food or animal food;
(2) Any person that engages in the business of buying or selling (as a poultry products broker, wholesaler, or otherwise) or transporting, in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any poultry;
(3) Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter.
(b) The required records are:
(1) Records, such as bills of sale, invoices, bills of lading, and receiving and shipping papers, giving the following information with respect to each transaction in which any poultry or poultry carcass, or part or product of a poultry carcass, is purchased, sold, shipped, received, transported, or otherwise handled by said person in connection with any business subject to the Act.
(i) The name or description of the poultry or other articles;
(ii) The net weight of the poultry or other articles;
(iii) The number of outside containers;
(iv) The name and address of the buyer of the poultry or other articles sold by such person, and the name and address of the seller of the poultry or other articles purchased by such person;
(v) The name and address of the consignee or receiver (if other than the buyer);
(vi) The method of shipment;
(vii) The date of shipment; and
(viii) The name and address of the carrier.
(2) Guaranties provided by suppliers of packaging materials under § 381.144.
(3) Records of canning as required by Subpart X of this Part 381, of Subchapter C, 9 CFR, Chapter III.
(4) Records of irradiation as required by section 381.149 of this Part.
(5) Records of nutrition labeling as required by Subpart Y of this Part.

(Approved by the Office of Management and Budget under OMB #0583-0015)

§ 381.176 Place of maintenance of records.

Every person engaged in any business described in § 381.175(a) shall maintain the records required by § 381.175 at the place of business where such

business is conducted, except that, if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records shall be kept in a safe place at the prescribed location in accordance with good commercial practices.

§ 381.177 Record retention period.

(a) Every record required to be maintained under this subpart shall be retained for a period not to exceed 2 years after December 31 of the year in which the transaction to which the record relates has occurred, and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such record under this subpart.

(b) Records of canning as required by Subpart X of this Part 381, Subchapter C, 9 CFR Chapter III, shall be retained as required in § 381.307; except that records required by § 381.302(b) and (c) shall be retained as required by those sections.

§ 381.178 Access to and inspection of records, facilities and inventory; copying and sampling.

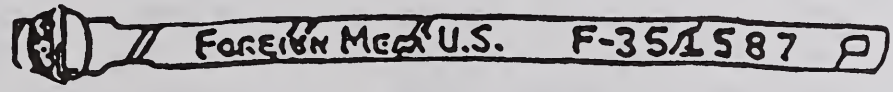
Every person within any of the classes specified in § 381.175(a) shall, upon the presentation of official credentials by any authorized representative of the Secretary, during ordinary business hours, permit such representative to enter his or its place of business and examine the records required to be kept by § 381.175(b) and the facilities and inventory pertaining to the business of such person subject to the Act, and to copy all such records, and to take reasonable samples of the inventory upon payment of the fair market value therefor. Any necessary facilities (other than reproduction equipment) for such examination and copying of records and for such examination and sampling of inventory shall be afforded to such authorized representative of the Secretary.

§ 381.179 Registration.

(a) Except as provided in paragraph (c) of this section, every person that engages in business, in or for commerce, as a poultry products broker, renderer, or animal food manufacturer, or engages in business in commerce as a

*U.S. G.P.O.:1996-417-250:40019

(h) The official mark for use in sealing means of conveyance used in transporting poultry products under any requirement in this part shall be the inscription and a serial number as shown below,[1] and any seals approved by the Administrator for applying such mark shall be an official device.



§381.201 Means of conveyance and equipment used in handling poultry products offered for entry to be maintained in sanitary condition.

Compartments of steamships, railroad cars, and other means of conveyance transporting any poultry product to the United States, and all chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling any poultry product offered for entry into the United States, shall be maintained in a sanitary condition.

§ 381.202 Poultry products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made; denaturing procedures.

(a)(1) Program inspectors shall report their findings as to any product which has been inspected in accordance with this Part, to the Director of Customs at the original port of entry.

(2) When product has been identified as "U.S. refused entry," the inspector shall request the Director of Customs to refuse admission to such within the time specified in this section, unless the owner or consignee, within the specified time, causes it to be destroyed by disposing of it under the supervision of a Program employee so that the product can no longer be used as human food, or by converting it to pet food uses, if permitted by the Food and Drug Administration. The owner or consignee of the refused entry product shall not transfer legal title to such product, except to a foreign consignee for direct and immediate exportation or to an end user, e.g., an animal food manufacturer or a renderer, for destruction for human food Purposes. "Refused entry" product must be delivered to and used by the manufacturer or renderer within the 45-day time limit. Even if such title is illegally transferred, the subsequent purchaser will still be required to export the product or have it destroyed as specified in the notice under paragraph (a)(4) of this section.

(3) No lot of product which has been refused entry may be subdivided during disposition pursuant to subparagraph (a)(2) of this section, except that removal and destruction of any damaged or otherwise unsound product from a lot destined for reexportation is permitted under supervision of USDA prior to exportation. Additionally, such refused entry lot may not be shipped for export from any port other than that through which the product came into the United States without the expressed consent of the Administrator, based on full information concerning the product's disposition, including the name of the vessel and the date of export. For the purposes of this paragraph, the term "lot" shall refer to that product

1/ The term "F-351587" is given as an example only. The serial number of the specific seal will be shown in lieu thereof.

identified on MP Form 410 in the original request for inspection for importation pursuant to § 381.198.

(4) The owner or consignee shall have 45 days after notice is given by FSIS to the Director of Customs at the original port of entry to take the action required in subparagraph (2) of this paragraph for refused entry product. Extension beyond the 45-day period may be granted by the Administrator when extreme circumstances warrant it; e.g., a dock workers' strike or an unforeseeable vessel delay.

(5) If the owner or consignee fails to take the required action within the time specified under subparagraph (4) of this paragraph, the Department will take such actions as may be necessary to effectuate its order to have the product destroyed for human food purposes. The Department shall seek court costs and fees, storage, and proper expenses in the appropriate forum.

(6) No product which has been refused entry and exported to another country pursuant to paragraph (a)(2) of this section may be returned to the United States under any circumstance. Any such product so returned to the United States shall be subject to administrative, detention in accordance with section 19 of the Act, and seizure and condemnation in accordance with section 20 of the Act.

(b) Upon the request of the Director of Customs at the port where a product is offered for clearance through the customs, the consignee of the product shall, at the consignee's own expense, immediately return to the Director any product which has been delivered to consignee under this subpart and subsequently designated "U.S. Refused Entry" or found in any respect not to comply with the requirements in this subpart.

(c) Except as provided in § 381.200 (a) or (b), no person shall remove or cause to be removed from any place designated as the place of inspection, any poultry product which the regulations in this subpart require to be marked in any way, unless the same has been clearly and legibly marked in compliance with this subpart.

(d) Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: Provided, That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, and such supervisor shall determine whether the inspector's decision was correct. Review of such appeal determination, when requested, shall be made by the immediate supervisor of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of $9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner * approved by the inspector pending completion of an appeal inspection. * * * *

(e) All condemned carcasses, or condemned parts of carcasses, or other condemned poultry products, except those condemned for biological residues, shall be disposed of by one of the following methods, under the supervision of an inspector of the Inspection Service. (Facilities and materials for carrying out the requirements in this section shall be furnished by the official establishments.)

(1) Steam treatment (which shall be accomplished by processing the condemned product in a pressure tank under at least 40 pounds of steam pressure) or thorough cooking in a kettle or vat, a sufficient time to effectively destroy the product for human food food purposes and preclude

(d) The import warning notice prescribed in §381.200(c) is an official mark.

(e) The ordering and manufacture of brands shall be in accordanoe with the provisions contained in §317.3(c) of the Federal meat inspection regulations.

(f) The inspection legend may be placed on containers of product before completion of official import inspection if the containers are being inspected by an import inspector who reports directly to an Import Field Office Supervisor; the product is not required to be held at the establishment pending the receipt of laboratory test results; and a written prooedure for controlled stamping, submitted by the import establishment and approved by the Director, Import Inspection Division, is on file at the import inspection facility where the inspection is to be performed.

(1) The written procedure for controlled pre-stamping should be in the form of a letter and shall include the following: (i) that stamping under this part will be limited to those lots of product which can be inspectod on the day that certificates for the product are examined; (ii) that all product which has been pre-stamp will be stored in the facility where the import inspection will oocur; (iii) that inspection marks applied under this part will be removed fram any lot of product subsequently refused entry on the day the product is rejected; and (iv) that the establishment will maintain a daily stamping log containing the following information for each lot of product: the date of inspection, the country of origin, the foreign establishment number, the product name, the number of units, the shipping container marks, and the MP-410 number covering the product to be inspected. The daily stamping log must be retained by the establishment in accordance with the requirements of §381.177.

(2) An establishment's controlled pre-stamping privilege may be cancelled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that the establishment has failed to comply with the provisions of this part or any conditions imposed pursuant thereto. If the cancellation is oral, the decision and the reasons therefor shall be confirmed in writing, as promptly as circumstances allow. Any person whose controlled pre-stamping privilege has been cancelled may appeal the decision to the Administrator, in writining, within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the controlled pre-stamping privilege was wrongfully cancelled. The Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such oonflict. Rules of practice concerning such a hearing will be adapted by the Administrator. The cancellation of the controlled pre-stamping, privilege will be in effect until there is a final determination of the proceeding.

(Approved by the Office of Management and Budget under control number 0583-0015)

§ 381.205 Labeling of immddiate containers of poultry products offered for entry.

(a) Immediate containers of poultry products imported into the United States shall bear a label printed in English showing in accordance with Subpart N of this part all information required by that section (except that the inspection mark and establishment number assigned by the foreign poultry inspection system and certified to the Inspection Service shall be shown instead of the official dressed poultry identification mark or other official inspection legend, and official establishment number); and in addition the label shall show the name of the country of origin preceded by the words "Product of," which statement shall appear immediately under the name of the product.

(b) The labels shall not be false or misleading in any respect.

(c) All marks and other labeling for use on or with immediate containers * shall be approved for use by the Food Safety and Inspection Service in * accordance with §§ 381.132 and 381.133 before products bearing such marks * and other labeling will be permitted for entry into the United States. *

§ 381.206 Labeling of shipping containers of poultry products offered for entry.

Shipping containers of imported pcultry products are required to bear in a prominent and legible manner the name of the product, the name of the country of origin, the foreign inspection system establishment number of the establishment in which the product was processed, and the inspection mark of the courtry of origin. Labeling on shipping oontainers shall be examined at the time of inspection in the United States and if found to be * false or misleading, the product shall be refused entry. All labeling used * with a shipping container of imported poultry products must be approved in * accordance with subpart N of this part. *

§ 381.207 Small importations for consignee's personal use, display, or laboratory analysis.

Any poultry product (other than one which is forbidden entry by other Federal law or regulation) from any country in quantities of less than 50 pounds net weight, exclusively for the personal use of the consignee, or for display or laboratory analysis by the consignee, and not for sale or distribution; which is sound, healthful, wholesame, and fit for human food, and which is not adulterated and contains no substance not permitted by the Act or regulations, may be imported into the United States without a foreign inspection certificate, and such product is not required to be inspected upon arrival in the United States and may be shipped to the consignee without further restriction under this part, except as provided in § 381.199(c):

United States Department of Agriculture
Food Safety and Inspection Service
Room 0157-South Building
Washington, DC
20250

OFFICIAL BUSINESS
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